

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEW ENGLAND COMPOUNDING
PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

MDL NO. 2419
Master Dkt. No. 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:
All Actions

**NON-PARTIES DR. O'CONNELL'S PAIN CARE CENTER AND DR. O'CONNELL'S
PAIN CARE CENTER, INC.'S OBJECTIONS AND MOTION TO QUASH SUBPOENA**

COME NOW Non-Parties Dr. O'Connell's Pain Care Center, and Dr. O'Connell's Pain Care Center, Inc. (collectively "PainCare"), by and through counsel, Shaheen & Gordon, P.A., and submit this objection to the subpoena of the Plaintiffs' Steering Committee ("PSC") and motion to quash on the grounds that (A) the subpoena improperly seeks protected health information and information protected by the New Hampshire physician-patient privilege without a showing adequate to overcome the privilege; (B) the subpoena is unduly burdensome and overly broad as the information it seeks is not reasonably calculated to lead to the discovery of admissible evidence; (C) the deposition subpoena is invalid because it violates the automatic stay, was not authorized by the Court, and imposes an undue burden; and (D) the time provided for compliance is not reasonable.

INTRODUCTION

PainCare is the leading medical practice in its region dedicated exclusively to pain management, with twelve offices in New Hampshire. Since the issue of alleged contamination of certain lots of methylprednisolone acetate furnished by New England Compounding Center ("NECC") first surfaced, PainCare and its employees have worked tirelessly with the CDC and state health authorities, and at great expense, to keep patients informed and to identify and treat

any potential medical issues arising in PainCare's patients as a result of exposure to contaminated NECC products. PainCare continues to see its patients regularly and to monitor any potential medical issues.

The PSC served an exhaustive non-party subpoena pursuant to Federal Rule of Civil Procedure 45 on two of PainCare's locations, requiring PainCare to produce records regarding the identity of PainCare's patients, documentation of PainCare's communications with NECC, and information about PainCare's insurance, corporate structure, and principals. *See* Subpoena to Dr. O'Connell's Pain Care Center and Dr. O'Connell's Pain Care Center, Inc., attached hereto as Exhibits A and B. The subpoenas also call for PainCare to designate and produce a witness for a deposition on July 25, 2013, at 9:00am.

To our knowledge, neither PainCare, nor any of its patients, is a party to this action, and no PainCare patient has filed suit against PainCare as a result of the allegedly contaminated lots of methylprednisolone acetate furnished by NECC. The subpoenas demand that PainCare produce an array of documents not kept in the ordinary course of business. They would require the production of privileged and confidential protected health information and would require PainCare to compile and create documents in response to the subpoenas. Counsel for PainCare has consulted with counsel for the PSC in an attempt to narrow the scope of the subpoenas. Because counsel for the PSC insists that privileged, protected health information be produced, at least with regard to the names of patients who were potentially exposed to contaminated NECC products, efforts to reach a mutually acceptable resolution have thus far been unsuccessful. PainCare now files these objections and motion to quash.

ARGUMENT

A. The Subpoena Improperly Seeks Protected Health Information and Information Protected by the New Hampshire Physician-Patient Privilege Without a Showing Adequate to Overcome the Privilege.

Fed. R. Civ. P. 45(c)(3)(A)(iii) requires a Court to quash or modify a subpoena that requires disclosure of privileged or other protected matter, when no exception or waiver applies. Responses to several of the questions posed by the subpoena would encompass privileged protected health information relating to non-party patients of PainCare, including Questions 1, 3, 4, and 5 (prescriptions submitted to New England Compounding Pharmacy, Inc. (“NECP”)); Question 6 (patient name, address, date of birth, identification of product administered, and date product was administered for all NECP products administered over a two-year period from October 6, 2010 to October 6, 2012); and Question 15 (any communications made in response to any recall notice regarding NECP products).

The information requested is protected by the physician-patient privilege, N.H. RSA 329:26, as well as by the HIPAA Privacy Rule, 45 C.F.R. Parts 160 and 164.

1. PainCare is Obligated to Safeguard Patient Information.

PainCare has a legal, ethical, and moral obligation to its patients to safeguard their privileged protected health information. As the Seventh Circuit has recognized, if a provider “cannot shield the medical records of its . . . patients from disclosure in judicial proceedings . . . the [provider] will lose the confidence of its patients, and persons with sensitive medical conditions may be inclined to turn elsewhere for medical treatment.” *Nw. Mem’l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004). Courts recognize the potential psychological harm to patients and potential cost in lost goodwill to the health care provider as valid factors that must

be weighed against the probative value of the records in considering whether a subpoena for protected health information should be enforced. *See id.* at 930.

Contrary to the view of the PSC, these concerns are not overcome simply through obtaining a court order that satisfies the procedural requirements of HIPAA. Courts considering whether to issue an order requiring the disclosure of protected health information must weigh the burdens and benefits of disclosure, and must consider state privilege law. *See, e.g., id.* at 927-929 (weighing the lack of probative value of the records with the loss of privacy by the patients, and holding that quashing the subpoena was required); *see also In re Sealed Case (Med. Records)*, 381 F.3d 1205, 1218 (D.C. Cir. 2004) (holding that courts may not compel production of medical records, even when they are not privileged, “without weighing the probative value of each of the non-privileged documents against the extent of the intrusion into the appellant’s legitimate privacy interests”). No such weighing has taken place here.

Nor can compliance with HIPAA alone satisfy New Hampshire law, which imposes independent burdens and obligations. HIPAA does not preempt state laws where “[t]he provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification” contained in the HIPAA Privacy Rule. 45 C.F.R. § 160.203, 160.203(b). The New Hampshire physician-patient privilege is one such law, and it places confidential relations and communications between physicians and patients “on the same basis as those provided by law between attorney and client.” N.H. RSA 329:26. New Hampshire courts have supported disclosure of such privileged communications only when “(1) a statute specifically authorizes disclosure; (2) a sufficiently compelling countervailing consideration is identified; or (3) disclosure is essential under the specific circumstances of the case.” *In re Grand Jury Subpoena for Medical Records of Curtis*

Payne, 150 N.H. 436, 440-41 (2004) (internal citations omitted). “To establish essential need, the party seeking the privileged records must prove both that the targeted information is unavailable from another source and that there is a compelling justification for its disclosure.” *Id.* at 442. The New Hampshire Supreme Court has also recognized that when medical records are sought from a provider, even by the government, the individual whose records are at issue must have an opportunity to object. *See In re Search Warrant for Medical Records of C.T.*, 160 N.H. 214, 226 (2010). The subpoena makes no provision for such an objection before requiring that privileged health information be disclosed.¹

New Hampshire patients rely on New Hampshire’s strong policy of privacy of health information, and that policy must be upheld by this court. *See In re Grand Jury Subpoena for Medical Records of Curtis Payne*, 150 N.H. at 440 (“Traditionally, we have carefully guarded the confidential relationship between patients and their medical providers . . .”). The claims in this MDL are state law tort claims, and thus this court must apply state law privileges. *See Fed. R. Evid.* 501. Even where such privileges do not formally apply, federal courts have relied upon them in quashing a subpoena. *See Nw. Memorial Hosp.*, 362 F.3d at 932 (holding that even where state law does not supply the rule of decision, “comity ‘impels federal courts to recognize state privileges where this can be accomplished at no substantial cost to federal substantive and procedural policy.’”); *see also In re Sealed Case (Med. Records)*, 381 F.3d at 1216 (endorsing Seventh Circuit’s approach in *Northwestern Memorial Hospital*). Where, as here, the privilege is directly applicable, it cannot be overcome without establishing a compelling countervailing

¹ Even in response to a grand jury subpoena or a court-issued search warrant in a criminal matter where the medical records implicated are those belonging to a potential criminal suspect, in which the balance weighs more in favor of disclosure than in a typical civil case, the New Hampshire Supreme Court has required significant showings and implemented robust procedures to safeguard patients’ privileged medical information and protect their privacy. *See In re Grand Jury Subpoena for Medical Records of Curtis Payne*, 150 N.H. at 440-41; *see also In re Search Warrant for Medical Records of C.T.*, 160 N.H. at 226.

consideration or essential need as required by New Hampshire law. *See In re Grand Jury Subpoena for Medical Records of Curtis Payne*, 150 N.H. at 440-42. PainCare reiterates that to its knowledge, no patient has sued PainCare, and no patient has provided a release authorizing records to be turned over to the PSC. In the absence of a valid authorization, release, or a showing sufficient to satisfy New Hampshire law, PainCare cannot be compelled to release the records.

2. Disclosure of Patient Names Would Impose an Unreasonable Burden on PainCare and its Patients, All of Whom are Non-Parties.

As discussed above, case, statutory, and administrative law at the state and federal level recognizes patients' strong interest in the privacy of their medical records. Neither PainCare nor any of its patients are parties to this action or clients of the attorneys requesting the documents. PainCare's patients have strong privacy interests in their health information, and such interests are privileged under New Hampshire law and protected under federal law. Treatment for pain is a private and personal matter and many PainCare patients are sensitive about their treatment and the fact that they are receiving it. Patient records contain highly sensitive personal information regarding diagnosis, treatment, personal and psychological issues, addiction, and more. For this reason, PainCare strictly guards the identity of its patients consistent with the requirements of state and federal law and New Hampshire's strong tradition of respecting individual privacy.

The PSC will likely contend that disclosing patient names, addresses, dates of birth, identification of products administered, and the date of administration for every patient who received any NECC product over a two year period does not require producing patient records, but rather a mere "list." However, as detailed above, PainCare has significant concerns with disclosing patient identities, which are sensitive and privileged protected health information.

Moreover, because such information is not separately maintained in a list, disclosing it would require either producing patient records or generating documents that do not yet exist.

In addition, although the PSC has suggested that it may narrow the subpoena, at present, the subpoena seeks information about every patient who received any NECC product over a two year period. Requiring PainCare to compile names and contact information of every person who received an NECC product over two years would be highly costly and burdensome, if not impossible. PainCare has not separately maintained a list of all patients who received NECC products over a two-year period of time and their dates of administration, and it is improper to require a non-party to generate documents that do not yet exist in order to comply with a Rule 45 subpoena. *See, e.g., Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 168 F.R.D. 630, 633 (N.D. Ill. 1996) (“Rule 45 appears to contemplate that a non-party may be required to produce records that already exist and are under the non-party’s control, but does not contemplate that a non-party will be forced to create documents that do not exist.”); *see also, e.g., Georgacarakos v. Wiley*, No. 07-CV-01712-MSK-MEH, 2009 WL 924434, at *2 (D. Colo. Apr. 3, 2009) (“[I]f a requested document is not in the possession of a party or non-party, such person need not create the non-existent document.”).

Even if it were proper to require the generation of such a list, there is no evidence of harm caused by NECC products from lots other than those that were identified as contaminated, and the provision of notice to individuals who may have received such products will only cause unnecessary anxiety, fear, and trauma as it causes individuals to believe (wrongly) that they are at risk of grievous harm. Allowing such discovery would also undermine the deliberate and careful investigative process that the CDC, state health authorities, and PainCare undertook in the wake of disclosure of the NECC contamination to appropriately respond and minimize both

potential harm to patients and the anxiety that accompanies any such situation. Moreover, to compile such a list would likely be impossible. Patient records do not ordinarily detail the manufacturer of injections received, and at the very least, compiling a list would require a detailed review of patient medical records and speculative determinations regarding which manufacturers' injections might have been used for which patients. The resulting list would be both over- and under-inclusive. PainCare, moreover, has thousands of patients, many of whom are seen regularly and hence have lengthy records. Conservatively, reviewing all such records would consume hundreds of hours of employee time, and would take multiple employees months to accomplish. The law does not require non-party PainCare to undertake this extraordinary burden to provide a meager and uncertain benefit to the PSC in this lawsuit.

3. No Compelling Countervailing Consideration Has Been Identified, Nor is Disclosure Essential Under the Specific Circumstances of the Case.

When asked why it is seeking patient names, the PSC has stated that the reason it must have patient names is in order to provide potential plaintiffs with notice of the upcoming bar date in the bankruptcy action. *See In re New England Compounding Pharmacy, Inc.*, No. 12-19882-HKB (Bankr. D. Mass.). This is not a sufficiently compelling consideration to overcome the burden on PainCare and its patients or the significant privacy concerns identified above, nor does it render disclosure essential. Accordingly, the subpoena must be quashed.

There is no compelling or essential need for disclosure here. As a preliminary matter, the Trustee has already filed a motion in the bankruptcy action seeking to require those who received and administered or distributed NECC products to patients over a two year period to give notice of the bar date to their patients, or, in the alternative, to provide contact information to the Trustee so that he may provide notice. *See In re New England Compounding Pharmacy, Inc.*, No. 12-19882-HKB (Bankr. D. Mass.), *Chapter 11 Trustee's Motion for Order* (Dkt. No. 263), ¶

38, (hereinafter “Bar Date Motion”). Although PainCare has concerns with the proposed procedure and its scope, and expects to file an objection to it with the bankruptcy court, disclosure in this action cannot be *essential* when there is an alternative procedure that is less invasive of patient privacy and accomplishes the PSC’s stated purpose.

As the Bankruptcy Trustee himself acknowledged in a Motion recently filed in the bankruptcy action, the law only requires direct notice to “known creditors”; that is, creditors whose identity is known to the debtor. Bar Date Motion ¶¶ 33-37. The Trustee has stated that the process of identifying all persons who might have received allegedly tainted NECC products cannot be determined “without engaging in lengthy, protracted, costly, and burdensome discovery” of former NECC customers such as PainCare. *See id.* ¶ 33. Yet the PSC unreasonably wishes to shift the burdens and costs of such discovery onto PainCare by requiring PainCare to search its files and provide notice to each patient who may possibly have received an NECC product, however remote the possibility that he or she may wish to file a claim.

As the Trustee recognizes, the provision of constructive notice via publication to all other creditors is a well-recognized practice. *See id.* ¶¶ 34-37. Such notice is more than adequate under the circumstances of this case. *See id.* ¶ 39 (“[T]he Trustee submits that publication notice is necessary and appropriate, and sufficient notice for those persons who may have suffered damages allegedly resulting from the Debtor’s products, but for whatever reason have neither filed claims nor are known after a careful search of the Debtor’s books and records, all at least 10 months after the Debtor last shipped any of its products.”). Allowing notice by publication appropriately avoids burdening non-parties such as PainCare with the need to search their records and give notice to every potential claimant, however remote. PainCare is not aware that any of its patients are involved in litigation against either PainCare or NECC.

As the Trustee acknowledges in his motion, it has been over ten months since the last NECC products shipped. *Id.* ¶ 39. It is an understatement to say that the alleged contamination involving NECC products has been well-publicized, particularly in New Hampshire, a part of the Greater Boston media market where NECC was based. Virtually every patient of PainCare, whether he or she was exposed to NECC products or not, is aware of the alleged contamination as a result of the publicity surrounding it and the extraordinary private and governmental response undertaken to examine and treat those who may have been affected by it. Nor is this a situation, such as that involved in some financial-oriented class actions, where victims do not necessarily know that they have been harmed until they receive notice of a class action certification or settlement. Those who may have been harmed by NECC products are well aware of their harm and of the opportunity to file suit. By the time of the proposed bar date, it will have been well over a year since the harm first surfaced, sufficient time for someone potentially injured by an NECC product to contact an attorney and investigate any potential claims.²

Finally, the PSC cannot show an essential need for disclosure because the PSC can obtain like documents from their own clients, the providers of their clients, and the defendants in this action. The subpoena served on PainCare is quite broad and untailored to any particular concern related to PainCare or its patients. There is simply no reason to burden PainCare and its patients with this subpoena, especially on such a wholesale basis.

4. Disclosure is Not Warranted Here.

² The PSC will likely counter that there exist latent harms that may not surface for months or even years after one was exposed to a contaminated NECC product. Regardless of the scientific merit of such a contention, providing notice of the bar date will not be of any assistance to those who cannot yet know whether they have been injured. If the PSC's assertion of latent harms has validity, the solution is to extend the bar date and/or to set aside money in a fund for unknown claimants whose injuries have not yet manifested, not to require PainCare to disclose the identities of a broad group of patients, breaching the privacy of many individuals who have not suffered and will not suffer any harm.

PainCare cannot be required to disclose names of its patients unless such disclosure would comply with both federal and New Hampshire law. The meager and uncertain benefits of disclosure do not outweigh the strong burdens that disclosure would impose on non-parties PainCare and its patients. Nor has the physician-patient privilege been overcome, as disclosure would impose an unreasonable burden on non-party PainCare and its non-party patients, and the PSC has not identified any compelling countervailing consideration, nor shown why the disclosure of the names of PainCare's patients is essential. Accordingly, this court must quash the subpoena.

B. The Subpoena is Unduly Burdensome and Overly Broad as the Information it Seeks is not Reasonably Calculated to Lead to the Discovery of Admissible Evidence.

“Whether a subpoena places an undue burden on a party depends on many factors, such as the relevance of the documents sought, the necessity of the documents sought, the breadth of the request, the time period covered by the request, the particularity with which the documents are described, and the burden in fact imposed. In addition, a non-party is given consideration regarding inconvenience and expense.” *Demers v. LaMontagne*, No. Civ. A. 98-10762-REK, 1999 WL 1627978, at *2 (D. Mass. May 5, 1999) (citing *United States v. Concemi*, 957 F.2d 942, 949 (1st Cir. 1992); *Concord Boat Corp. v. Brunswick Corp.*, 169 F.R.D. 44, 49 (S.D.N.Y. 1996)) (internal citations omitted); *see also* Fed. R. Civ. P. 45(c)(2)(B)(ii) (“[T]he order [compelling production of materials] must protect a person who is neither a party nor a party’s officer from significant expense resulting from compliance.”). “[I]f the sought-after documents are not relevant, nor calculated to lead to the discovery of admissible evidence, then any burden whatsoever imposed would be by definition ‘undue.’” *Gonzales v. Google, Inc.*, 234 F.R.D. 674, 680 (N.D. Cal. 2006) (internal citations omitted).

Neither PainCare nor any of its patients are parties to the MDL. As discussed in detail above, the identity of PainCare patients who are not plaintiffs in the MDL is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence. The PSC has requested privileged protected health information of non-party patients from a non-party health care provider, PainCare, without obtaining any authorizations from the patients whose records are at issue. Such information has no relevance or bearing on the PSC's ability to prove its claims against NECC. Instead, its most apparent purpose would be to obtain information on additional potential clients for the PSC to represent, which is not a legitimate purpose for non-party discovery. PSC does not represent a class of all patients who received NECC's medications, and the private health information of patients not parties to the MDL is privileged, unrelated to the claims and defense in the MDL, and not the proper subject of a non-party subpoena.

The subpoena also seeks a vast amount of information other than information regarding specific patients. Among other things, it seeks any and all documents related to the procurement of several different preparations and solutions from New England Compounding Pharmacy, Inc. ("NECP") over a two-year period, any communications between PainCare and NECP over a two-year period, any information obtained by PainCare regarding NECP at any time, any communications between PainCare and any governmental agency in connection with the procurement of products from any compounding pharmacy, NECP marketing information, and recall notices received and communications in regard to such notices. PainCare does not have this information assembled in any one place, and it will accordingly take PainCare months to search its electronic and paper files in order to respond. Most significantly, the vast majority of this information has no bearing on any suit that is part of the MDL. The information that does bear upon the MDL can more easily be produced by NECC or other parties to the MDL, and

accordingly there is no reason to burden non-party PainCare with a request for production. In light of the fact that these requests go well beyond the timeframe, products, compounding pharmacies, and parties at issue in the present MDL, they constitute an undue burden, and a significant narrowing of the timeframe and scope of the PSC's requests is necessary to make the subpoena not constitute an undue burden on PainCare.

Finally, the subpoena seeks information regarding PainCare's insurance policies; its corporate structure, including its articles of incorporation, bylaws, and organizational charts; and the identity of its officers, directors, and owners. As PainCare is not a party, such requests have no relevance or necessity to any suit that is part of the MDL, are an improper invasion of PainCare's privacy, and are not reasonably calculated to lead to the discovery of admissible evidence. In the absence of a suit against PainCare, information regarding its insurance, corporate structure, and principals is simply not relevant to the pending action and production of this information should not be required.

PainCare need not submit itself, its patients, and their privileged protected health information to the PSC's fishing expedition. The subpoena places an undue burden on PainCare and should be quashed.

C. The Deposition Subpoena Is Invalid Because It Violates the Automatic Stay, Was Not Authorized by the Court, and Imposes an Undue Burden.

The proposed deposition would violate the automatic stay imposed by NECC's bankruptcy case. As the Defendant in this action, NECC has a right to participate in a deposition. Because it would affect NECC's rights, the proposed deposition would potentially violate the automatic stay imposed by 11 U.S.C. § 362(a).

The proposed deposition may also be invalid because it was not authorized by this court's order authorizing service of subpoenas.

Finally, the deposition subpoena must be quashed because it imposes an undue burden. In addition to the burdensome nature of the request for production of documents, the subpoena would require PainCare to educate a single employee on a vast array of records spread across multiple offices. Such a request is particularly unreasonable in light of the short timeframe afforded for compliance.

D. The Time Provided for Compliance Is Not Reasonable.

Finally, even if the subpoena were otherwise reasonable, the PSC has not provided PainCare with a reasonable amount of time with which to comply with its highly burdensome and broad subpoena. The subpoena was served on June 25 and demands production within 21 days, by July 16, 2013. Such an amount of time, even shorter than the 30-day period that *parties* typically have to respond to discovery requests, is nowhere near sufficient to afford PainCare time to search for and compile the necessary documents, provide those documents to counsel, have those documents reviewed for privileges and other potential bases for non-disclosure, and to stamp, copy, and turn them over to the PSC. Should PainCare be required to comply with such a burdensome subpoena, PainCare requests that the court require the PSC to reasonably compensate it for the time required to respond. Fed. R. Civ. P. 45(c)(3)(C)(ii).

CONCLUSION

For the foregoing reasons, PainCare requests that this Court issue an order quashing the subpoena. In the alternative, PainCare requests that this Court issue an order modifying the subpoena consistent with the objections raised above, provide PainCare with a reasonable amount of time to respond to the subpoena, and impose a requirement that PainCare will be reasonably compensated for the time required to respond to the subpoena.

Respectfully submitted,

Dr. O'Connell's Pain Care Center
Dr. O'Connell's Pain Care Center, Inc.

By Their Attorneys:

DATED: July 16, 2013

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CERTIFICATE OF SERVICE

I hereby certify that the within OBJECTIONS AND MOTION TO QUASH SUBPOENA filed through the ECF System will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on July 16, 2013.

DATED: July 16, 2013

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